REMARKS

A. Background

Claims 1-39 were pending in the application at the time of the Office Action. Claims 1-39 were rejected as being anticipated and/or obvious over cited prior art. By this response Applicant has amended claims 1, 3, 4, 13-15, 21, 33, and 39 and added new claim 40. As such, claims 1-40 are presented for the Examiner's consideration in light of the following remarks.

B. Proposed Claim Amendments

Please amend the claims in the manner indicated above, where an underline represents new text, and strikeouts are used to indicate deleted text. The amendments to claims 1, 3, 4, 13-15, 21, 33, and 39, as well as new claim 40 are fully supported by the application as originally filed. More particularly, the amendments to claims 1 and 13 are fully supported in the specification at paragraphs [0021-0033]. Additionally, amended claims 33 and 39 are fully supported in the specification at paragraphs [0033], and amended claim 33 is further supported by claim 13 as originally filed. Also, new claim 40 is supported by claim 28 as originally filed.

In view of the foregoing discussion, Applicant submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

C. Rejection on the Merits

35 U.S.C. §102(b)

Paragraphs 1-31 of the Office Action rejected claims 1-4, 6-12, 13-20, 24-27, and 33-39 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,823,891 to *Grim et al.* In

response thereto, Applicant respectfully asserts that Grim does not teach or suggest each and every element of the pending claims.

Before discussing the anticipatory rejection herein, it is thought proper to briefly state what is required to sustain such a rejection. As the Examiner is aware, the issue under § 102 (b) is whether the PTO has provided a single prior art reference that expressly or inherently describes each and every element set forth in the rejected claim. Verdegaal Bros v. Union Oil co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Accordingly, if the reference does not describe each and every element, the reference cannot anticipate the claim.

Grim teaches an orthopaedic support that is comprised of outer and inner resilient layers, wherein the outer resilient layer is comprised of neoprene or another material suitable for surrounding and supporting a portion of the human anatomy through compression (*see*, Abstract). The support is illustrated and described to be useful for supporting the knee, and provides a padded member to "locate the patella within the patellofemural joint" (*see*, Figures 1-7 and column 8, lines 60-67). As such, the padded member is illustrated to substantially encircle the patella in order to provide the proper positioning thereof with respect to the knee (*Id.*). Also, Grim is completely devoid of teaching or suggesting that the support can or needs to be combined with another support or compressive device.

Conversely, the pending application teaches a compression garment that can be used for compressive therapy to alleviate maladies such as lymphedema or other edemas, and recites in claims 1 and 13 a "plurality of spaced apart pressure projections bounding a plurality of spaced apart recessed flow paths." The Office Action asserts that the annular ring 98 as depicted in Figures 6 and 7 corresponds to the claimed "pressure projections." Applicant respectfully submits, however, that a single annular ring cannot comprise a "plurality of spaced apart pressure projections," as recited in

claims 1 and 13. Furthermore, because annular ring 98 bounds only a <u>single</u> pocket, annular ring 98 cannot bound a "plurality of spaced apart recessed flow paths," as also recited in claims 1 and 13.

Accordingly, Applicant respectfully asserts that Grim does not anticipate claim 1 or claim 13. Additionally, Claims 2-4, 6-12, and 14-20 depend from claim 1 or 13 and thus incorporate the limitations thereof. As such, Applicant submits that claims 2-4, 6-12, and 14-20 are distinguished over *Grim* for at least the same reasons as discussed above with regard to claims 1 and 13.

Applicant also submits that many of the dependent claims are also independently distinguished over the cited prior art. For example, claim 3 requires that the "backing comprises the woven fabric sheet" and further requires that the "pressure projections are woven into the woven fabric sheet." The Office Action states that claim 3 is anticipated by fabric layer 106 enclosing the pressure projections 98, as depicted in Figure 7 and described in column 9, lines 1-4. Applicant respectfully disagrees, Grim specifically discloses that "padded members 96 and 98 are each cut from a sheet of stock of a preferred resilient material which has been <u>laminated</u> with a preferred fabric layer." Col. 9, 12-14 (emphasis added). Accordingly, since the fabric layer of Grim is simply "laminated" onto the surface of padded member 98, padded member 98 is not "<u>woven into</u>" the fabric layer as required by claims 3 and 14.

Claims 4 and 15 recites that the "inner layer comprises a corduroy fabric." The Office Action states that "inner layer comprises a corduroy material (see col. 4 lines 15-20)" (see, page 3 paragraph 5). Applicant has analyzed the section of Grim referenced by the Office Action but can find no disclosure or suggestion to the use of "corduroy fabric." As such, claims 4 and 15 cannot be anticipated by Grim.

With regard to claim 24, the Office Action states that Grim teaches a "method for manufacturing a compression sleeve, the method comprising: stretching a cover layer comprised of a

resiliently stretchable sheet of material (see col. 3 lines 37-47)" (see, page 6, paragraph 21). The Office Action also states, "securing the exterior surface of the stretched cover layer to the interior surface of the inner layer (all layers are secured via an adhesive bonding; see col. 6 lines 50-67, col. 7 lines 1-7)" (Id.) Upon detailed review of the citations given in the Office Action, however, applicant has failed to find any disclosure or suggestion as to "stretching a cover layer" and "securing the exterior surface of the stretched cover layer to the interior surface of the inner layer," as recited in claim 24. That is, Grim simply does not disclose or suggesting securing the cover layer to the inner layer while the cover layer is "stretched." Thus, Grim does not teach or suggest at least one element claimed in claim 24, and thereby cannot anticipate the claim.

Claims 25-27 depend from claim 24 and thus incorporate the limitations thereof. As such, Applicant submits that claims 25-27 are distinguished over Grim for at least the same reasons as discussed above with regard to claim 24.

With regard to claim 33, the Office Action states that the "progressive pressure along the length of the hand or the foot received therein without the use of an external pressure force" is achieved in Grim by "the elastic nature of the tubular sleeve and the pressure projection points" (see, page 7, paragraph 26). Applicant respectfully disagrees. The support disclosed in Grim is directed toward a knee support. Grim is completely devoid of any teaching or suggesting of a "terminal portion having a proximal end and a distal end mounted at an end of the sleeve, the terminal portion having an interior surface encircling a channel adapted to receive a hand or foot of the patient," as recited in claim 33. More importantly, however, Grim clearly does not disclose or suggest the "terminal portion being configured to apply progressive pressure along the length of the hand or the foot when received therein without the use of an external pressure force, wherein the progressive pressure increases the pressure from the proximal end to the distal end of the

<u>terminal portion</u>," as also recited in claim 33. Thus, Grim does not teach or suggest each and every element of claim 33.

Claims 34-38 depend from claim 33, and thus incorporate the limitations thereof. As such, Applicant submits that claims 34-38 are distinguished over Grim for at least the same reasons as discussed above with regard to claim 33.

With regard to claim 39, the Office Action states that the "terminal portion being contoured to apply progressive pressure to the hand or foot along the length thereof without adjustment of applying external force to the terminal portion" is anticipated "due to the pressure projections see fig. 7 reference objects 98 and straps see fig. 5 reference objects 78 and 86" (see, page 8 paragraph 31). Applicant again asserts that Grim is void of any teaching of supporting a hand or foot. As such, applicant respectfully submits that Grim does not disclose or suggest "inserting an arm or a leg of a patient into a channel of a sleeve such that a corresponding hand or foot of the patent is received within a channel of a terminal portion having a proximal end and a distal end at the end of the sleeve, the terminal portion being contoured to apply progressive pressure to the hand or foot along the length thereof without adjustment or applying external force to the terminal portion, wherein the progressive pressure increases the pressure from the proximal end to the distal end of the terminal portion," as recited in claim 39.

In view of the foregoing, Applicant respectfully asserts that Grim does not teach or suggest each and every claimed element in claims 1-4, 6-12, 13-20, 24-27, and 33-39 and withdrawal of the rejections of the claims under U.S.C. § 102 (b) is respectfully requested.

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35 U.S.C. §103(a)

a. Rejections under Grim

In order to establish an obviousness-type rejection, the PTO must satisfy certain requirements. As the Examiner is aware, the issue under § 103 is whether the PTO has stated a case of *prima facie* obviousness. According to the MPEP § 2142, the Examiner has the burden and must establish a case of *prima facie* obviousness by showing some motivation in a prior art reference to combine that reference with other prior art, or modify that reference, to teach all of the claim limitations in the instant application and have some reasonable expectation of success. The Applicant respectfully asserts the Office Action has not satisfied the requirement for establishing a case of *prima facie* obviousness against the presently pending claims.

Paragraphs 32 and 33 of the Office Action rejected claim 5 under 35 U.S.C. § 103(a) as being unpatentable over the Grim patent. In response thereto, Applicant respectfully asserts that Grim does not teach or suggest each and every element of the pending claim, and that the proposed modification to Grim was only made in hindsight after first reviewing the Figures 5A-C in the Applicant's application.

With specific reference to claim 5, the Office Action states:

As to claim 5, Grim et al. does not disclose a compression garment as recited in claim 1, wherein the pressure projections comprise a plurality of elongated ribs. However, the applicant discloses alternative arrangements of the pressure projections in figures 5A-C. Grim et al. pressure projection would be considered as randomly disposed pressure projections disclosed in figures 5B-C. Therefore, it would have been obvious to one of ordinary skills in the art at the time of the invention to modify the randomly disposed pressure projections of Grim in order to provide the compression garment with an alternative arrangements of pressure projections as claimed in claim 5.

Office Action, page 9 (emphasis added).

The Office Action appears to assert that Grim discloses randomly disposed pressure projections and because the present invention discloses projections that are both randomly disposed and disposed in elongated ribs that it would therefore be obvious to one skilled in the art to modify the projections of Grim into elongated ribs. Applicant respectfully disagrees on several levels.

Initially, applicant submits that the pressure projections of Grim are not randomly disposed. Padded member 98, as identified earlier in the Office Action, comprises a single annular ring which is specifically positioned to "locate the patella within the patellofemural joint." Col. 8, lines 65-66. Applicant submits that Grim does not disclose or suggest padded member 98 having a configuration remotely similar to the configurations depicted in Figures 5B or 5C of the present invention.

Furthermore, as discussed in the present application, the claimed "elongated ribs" achieve a unique benefit in the present invention by forming low pressure flow paths through which fluid can flow out of the limb in cases of edema. The orthopedic support of Grim is not designed or intended for use with treating edema. Furthermore, padded member 98 is specifically designed as a circular ring to facilitate proper alignment of the patella. As such, not only is there no motivation to modify padded member 98 into elongated ribs but such a modification would destroy the intended function of padded member 98 in Grim.

Finally, Applicant directs attention to the MPEP § 2145, which sets forth the test for impermissible hindsight. The court has stated, "any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper." In re McLaughlin, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA)

1971). Thus, when Applicant's disclosure is used as the basis of an obviousness rejection, the rejection is improper for impermissible hindsight.

In the rejection to claim 5, the Office Action actually uses the Figures in Applicant's application in order to show that it would be obvious to modify Grim to obtain pressure projections that are "a plurality of elongated ribs." Since the Office Action identifies that both Applicant and Grim disclose "randomly disposed pressure projections" in order to substantiate the modification of Grim to included the "a plurality of elongated ribs" presently claimed, impermissible hindsight has been used.

In view of at least the forgoing, applicant respectfully requests that the rejection with regard to claim 5 be withdrawn.

b. Rejections under Grim and Arabeyre

Paragraphs 34-36 of the Office Action rejected claim 21 under 35 U.S.C. § 103(a) as being unpatentable over the Grim patent in view of U.S. Patent No. 5,497,513 to *Arabeyre et al.* Arabeyre discloses a "remedial support appliance . . . comprising an elasticated knit main portion for compressing a leg or an arm in order to treat venous or lymphatic insufficiency" (*see*, Abstract). More specifically, as depicted in Figures 1 and 2, the support appliance comprises a resilient stocking or sleeve that is worn directly over the arm or leg so as to constrict around the arm or leg, thereby treating the venous or lymphatic insufficiency. In contrast, the orthopedic support of Grim is for stabilizing and protecting an injured or strained body part such as the knee. As such, the Arabeyre and Grim devices are designed to perform completely unrelated functions. Accordingly, because the Grim devices does not function to treat the venous or lymphatic insufficiency, applicant fails to find

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any motivation as to why one skilled in the art would even attempt to apply the stocking of Arabeyre over the support of Grim.

Furthermore, because the socking of Arabeyre is designed to be worn directly over the limb, applicant submits that it is unlikely that the stocking could even be passed over the bulky support of Grim. Likewise, if the stocking was pulled over the support, such a configuration would almost certainly diminish the ability of the stocking to efficiently compress the body part surrounded by the Grim support, thereby defeating the function of the Arabeyre stocking.

At most, applicant asserts that if an individual wanted to treat both discrete ailments that are serviced by the Grim and Arabeyre devices, the individual would first apply the stocking directly over the limb and would then apply the Grim device over the stocking. This assembly, however, would not produce "a resiliently stretchable tubular sock that is selectively pulled over the body," as recited in claim 21.

In view of the foregoing, applicant submits that it would not be obvious to combine the references as asserted in the Office Action and thus withdrawal of the rejection of claim 21 is respectfully requested.

c. Rejections under Grim, Arabeyre, and Turtzo

Paragraphs 37-42 of the Office Action rejected claims 22 and 23 under 35 U.S.C. § 103(a) as being unpatentable over the Grim patent and Arabeyre patent in view of U.S. Patent No. 6,254,554 to *Turtzo*. In response thereto, Applicant respectfully asserts that it would not be obvious to combine Grim, Arabeyre, and Turtzo as suggested in the Office Action and that even if the references were so combined, the combination still does not teach or suggest each and every element of the pending claims.

Turtzo teaches a compression sleeve for treating lymphedema that is comprised of an outer inelastic fabric layer and an inner flexible sheet padding layer with a plurality of tightening straps (see, Abstract). The tightening straps are taught to be "disposed in close adjacent proximity to each other so that the compression gradient is not disrupted and also to minimize the potential for pockets of swelling from bulging out from beneath and between the straps" (see, column 3, lines 67 through column 4 lines 6). The inner padding layer is comprised of high density foam, and is "flat with no raised projections" (see, column 4, lines 38-43).

The Office Action states that it would be obvious "to modify the leg sleeve of Grim et al in view of Turtzo in order to construct a tubular sleeve for the hand portion with the same compressive concept and constructive parts as disclosed by Grim" (see, pages 10-11, paragraph 39). Applicant disagrees. As noted above, Turtzo teaches that the straps be "disposed in close adjacent proximity to each other so that the compression gradient is not disrupted and also to minimize the potential for pockets of swelling from bulging out from beneath and between the straps." If the straps of Turtzo were adjacently positioned and tightened along the length of Grim to achieve the objective of Turtzo, the support of Grim would no longer be flexible at the knee, thereby destroying the intended function of Grim which is to provide a support that can be used in normal activity. If the straps were not adjacently positioned and tightened along the length of the Grim, the function of the Turtzo patent would be destroyed. Accordingly, because the Grim and Turtzo devices service different and mutually exclusive functions, applicant submits that it would not be obvious to combine the teachings of Turtzo and Grim as proposed in the Office Action.

Additionally, Applicant respectfully asserts that Turtzo teaches away from the claimed invention. In part, this is because Turtzo specifically teaches that the inner high density foam is "flat with no raised projections." Since Turtzo specifically teaches away from such raised projections, the

presently claimed "plurality of spaced apart pressure projections bounding a plurality of spaced apart recessed flow paths therebetween" is not obvious, and there is no motivation to modify or combine Turtzo with any reference in order to provide the pressure projections. Thus, a study of the teachings and suggestions of Turtzo teaches away from the claimed invention.

In view of the foregoing, Applicant respectfully asserts that the combination of *Grim*, Arabeyre, and Turtzo does not teach or suggest each and every claimed element, and that Turtzo actually teaches away from the presently claimed invention. As such, no case of *prima facie* obviousness has been made against claims 22-23. Thus, Applicant respectfully submits that claims 22-23 are allowable over the cited references and respectfully requests that the rejections of claims under U.S.C. § 103 be withdrawn.

c. Rejections under Grim, Arabeyre, and Levine

Paragraph 43-51 of the Office Action rejected claims 28-32 under 35 U.S.C. § 103(a) as being unpatentable over the Grim and Arabeyre patents in view of U.S. Patent No. 4,476,857 to Levine. In response thereto, Applicant respectfully asserts that the combination of references is improper and that such a combination fails to teach or suggest each and every element of the claimed invention.

With regard to claim 28, the Office Action again asserts, as discussed above with regard to claim 21, that it would be obvious to apply the sock of Arabeyre over the support of Grim. The Office Action also teaches that Levine teaches removable straps that that it would be obvious to attach removable straps to the support of Grim. Applicant disagrees.

Levine teaches an arm support that includes nylon covered neoprene sleeve having "an upper and a lower elastic strip or closure <u>each attached</u> adjacent a different end of the sleeve" (see, Abstract and Figure 1). In contrast to the assertion of the Office Action, applicant respectfully

submits that Levine does <u>not</u> disclose or suggest bands 14 and 16 being removable from sleeve 12, Rather, Levine teaches that "bands 14 and 16 may be sewn, bounded, or the like to the sleeve." Col. 3, lines 28 and 29. More importantly, however, for the same reasons as discussed above with regard to claim 21, applicant respectfully submits that it would not be obvious to apply the sock of Arabeyre over the support of Grim. As such, applicant submits that it would not be obvious to combine the references as suggested and thus withdrawal of the rejection of claim 28 is respectfully requested.

Claims 29-32 depend from claim 28, and thus incorporate the limitations thereof. As such, Applicant submits that claims 29-32 are distinguished over *Grim*, *Arabeyre*, and *Levine* for at least the same reasons as discussed above with regard to claim 28.

D. <u>Conclusion</u>

Applicant notes that this response does not discuss every reason why the claims of the present application are distinguished over the cited prior art. Most notably, Applicant submits that many if not all of the dependent claims are independently distinguishable over the cited prior art. Applicant has merely submitted those arguments which it considers sufficient to clearly distinguish the claims over the cited prior art.

In view of the foregoing, Applicant respectfully requests the Examiner's reconsideration and allowance of claims 1-40 as amended and presented herein.

In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Dated this <u>6</u> day of May 2005.

Respectfully submitted,

DANA L. TANGREN U

Attorney for Applicant

Registration No. 37,246 Customer No. 022913

Telephone No. 801.533.9800

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